

### **REMARKS**

The Final Office action dated June 30, 2009 is acknowledged. Claims 1-40 are pending in the instant application. According to the Office action, claims 1-15 and 25-40 have been rejected, claims 2 and 39 have been objected to and claims 16-24 and 38 have been withdrawn. By the present response, claims 1 and 37 have been amended and claim 2 has been canceled. The subject matter of claim 2 has been incorporated into independent claim 1. The Applicants thank the Examiner for withdrawing the various prior objections and rejections, as detailed on pages 4-5 of the Final Office action. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

### **Claim Objections**

Claims 2 and 39 have been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Examiner states that both claims expand the scope of the claimed active agent to include “pharmaceutically acceptable salts of deoxypeganine and pharmaceutically acceptable salts of a derivative of deoxypeganine.” Claim 2 has been canceled, and claim 1 has been amended to incorporate the relevant subject matter thereof. Withdrawal of this objection is respectfully requested.

### **Rejection of Claims 2 and 37 under 35 U.S.C. 112, second paragraph**

Claims 2 and 37 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner states that

claim 2 recite the limitation “said at least one active substance is selected from the group consisting of pharmaceutically acceptable salts of deoxypeganine and pharmaceutically acceptable salts of a derivative of deoxypeganine,” but that there is insufficient antecedent basis for the “salt” limitations in claim 1. Claim 1 has been amended accordingly and claim 2 has been canceled. Withdrawal of this rejection is requested.

The Examiner also states that claim 12 had been amended such that the limitation reciting “with a delay in time” has been removed. Thus, claim 37 lacks sufficient antecedent basis to claim 12. Claim 37 has been amended accordingly. Withdrawal of this rejection is requested.

**Rejection of Claims 1-15 and 25-37 under 35 U.S.C. 103(a)**

Claims 1-3, 5, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2007/0190117 (Asmussen, et al.) in combination with U.S. Patent No. 6,599,511 (Asmussen, et al.). The Examiner argues that ‘117 teaches a film-shaped medicament for buccal administration of galanthamine and at least one further pharmaceutically active substance, which is preferably selected from the group comprising acetylcholinesterase inhibitors (Abstract and claim 10), as well as that the film-shaped medicament has a bilayer or multilayer structure wherein at least one of the layers contains the active substance. However, the Examiner acknowledges that ‘117 does not further teach any specific examples of acetylcholinesterase inhibitors which may be incorporated into the film-shaped dosage form.

The Examiner refers to ‘511 for teaching the use of the compound desoxypeganine (1,2,3,9-tetrahydropyrrolo[2,1-b] quinazoline; deoxypeganine) which is a

noted inhibitor of acetylcholinesterase in orally, transdermally or sublingually administered pharmaceutical preparations. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to prepare a buccally-administrable, film-shaped dosage form comprising an acetylcholinesterase inhibitor such as deoxypeganine and/or its hydrochloride salt, and at least one other non-deoxypeganine-based active compound such as galanthamine.

Claims 4, 6-13, 15 and 27-37 have been rejected as being unpatentable over the combination of Asmussen, et al. '117 and Asmussen, et al. '511. The Examiner argues that '117 teaches the limitations of these claims, with the exception of teaching that the acetylcholinesterase inhibitor active compounds contribute to these percentages, or if they do, it is not expressly taught how much is attributed to said inhibitors. The Examiner refers to '511 for expressly teaching the multilayered dosage form as comprising a preferred percent weight range of 5-20% by weight of the desoxypeganine-based active substance. The Examiner further states that since only one reservoir layer is described in the delivery device, the layer containing the desoxypeganine-based drug – it then follows that the overall device contains the claimed amount of active compounds as well.

The Examiner also states that '117 fails to teach the percent weight ranges of desoxypeganine-based active substance either within the reservoir layer or the overall medicament. However, the Examiner concludes that since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. The Examiner concludes that it would have been obvious to one of

ordinary skill in the art to prepare a film-shaped dosage form comprising a deoxypeganine-based active substance at least one other active substance such as galanthamine and format the structure of the dosage form to produce the instantly claimed invention. The Examiner also concludes that in view of the combination of teachings, it would have been obvious to one of ordinary skill in the art to prepare a film-shaped dosage form comprising a deoxypeganine-based active compound and at least one other active compound such as galanthamine and to format the structure of the dosage form as expressly taught by '117 to produce the presently claimed invention.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention for the reasons set forth in the prior Office action response. Additionally, even if one skilled in the art were to consider the combined teachings of the prior art, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully point out that Asmussen, et al. '117 has a publication date of August 16, 2007, a US national phase filing date of October 17, 2006 and a PCT filing date of April 23, 2004. However, the present application has a priority date of

November 24, 2003, which antedates the cited Asmussen, et al. '117 reference. A certified English translation of German application number 103 54 894.7 – the priority application in the instant case – is submitted herewith. Therefore, it is submitted that Asmussen, et al. '117 should be withdrawn as a reference.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the prior art of record and that each and every element of the present invention recited in the present claims is not set forth in the prior art. Moreover, one skilled in the art would not be motivated to combine the teachings of the prior art references of record to arrive at the presently claimed invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

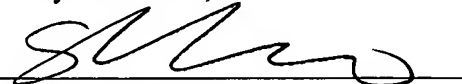
#### Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

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D. Peter Hochberg Co., L.P.A.  
1940 East 6<sup>th</sup> Street, 6<sup>th</sup> Floor  
Cleveland, OH 44114  
(216) 771-3800

Respectfully submitted,

By:   
Sean F. Mellino  
Reg. No. 48,817